

Patent
254/304

AMENDMENTS

IN THE CLAIMS:Please delete claims 8 and 9.Please amend specified claims to read as follows:

Sub E2
B1

1. A controlled, sustained release progressive hydration pharmaceutical composition in the form of a tablet, comprising:

an effective amount of an active ingredient that is metabolized by 5 α -reductase,

a bioadhesive, water insoluble, water-swellaable cross-linked polycarboxylic polymer,

and

a water soluble polymer,

wherein said composition is formulated in a dry state to deliver, upon administration of said tablet to a mucosal surface of a mammal, said active ingredient to the bloodstream of said mammal.

Sub E3
B2

7. A method of delivering to a mammal an active ingredient that is metabolized by 5 α -reductase, comprising administering said active ingredient via a progressive hydration bioadhesive composition to a mucosal surface of the mammal, wherein said composition is formulated as a dry tablet that includes

(a) said active ingredient,

(b) a bioadhesive, water insoluble, water swellable cross-linked polycarboxylic polymer, and

(c) a water-soluble polymer.

Patent
254/304

The amended claims in marked-up form are as follows:

1. (Twice Amended) A controlled, sustained release progressive hydration pharmaceutical composition in the form of a tablet, comprising:

an effective amount of an active ingredient that is metabolized by 5 α -reductase,

a bioadhesive, water insoluble, water-swellaable cross-linked polycarboxylic polymer,

and

a water soluble polymer,

wherein said composition is formulated in a dry state to deliver, upon administration of said tablet to a mucosal surface of a mammal, said active ingredient to the bloodstream of said [a] mammal [through a mucosal surface of the mammal].
7. (Amended) A method of delivering to a mammal an active ingredient that is metabolized by 5 α -reductase, comprising administering said active ingredient via a progressive hydration bioadhesive composition [through] to a mucosal surface of the mammal, wherein said composition is formulated as a dry tablet that includes

(a) said active ingredient,

(b) a bioadhesive, water insoluble, water swellaable cross-linked polycarboxylic polymer, and

(c) a water-soluble polymer.

Patent
254/304Please add the following new claims 17 to 30:

17. The pharmaceutical composition of claim 6, wherein said composition is formulated to deliver said testosterone via the mammal's buccal cavity.
18. The pharmaceutical composition of claim 6, wherein said composition is formulated to deliver said testosterone via the mammal's vaginal cavity.
19. The method of claim 10, wherein said composition is administered through the mammal's buccal cavity.
20. The method of claim 10, wherein said composition is administered through the mammal's vaginal cavity.
21. The controlled, sustained release progressive hydration composition of claim 14, wherein said composition is formulated to deliver said testosterone via the mammal's buccal cavity.
22. The controlled, sustained release progressive hydration composition of claim 14, wherein said composition is formulated to deliver said testosterone via the mammal's vaginal cavity.
23. A pharmaceutical composition comprising:
- testosterone,
 - a bioadhesive, water insoluble, water-swellaable cross-linked polycarboxylic polymer,
 - and a water soluble polymer,
- wherein said composition is formulated to deliver a therapeutically effective amount of said testosterone to the bloodstream of a mammal through a mucosal surface of the mammal.
24. The pharmaceutical composition of claim 23, wherein said composition is formulated to deliver said testosterone via the mammal's buccal cavity.

Patent
254/304

25. The pharmaceutical composition of claim 23, wherein said composition is formulated to deliver said testosterone via the mammal's vaginal cavity.

26. A controlled, sustained release progressive hydration composition for delivering testosterone to the bloodstream of a mammal, comprising:

a bioadhesive, water insoluble cross-linked polycarboxylic polymer,

a water soluble polymer,

and testosterone,

wherein said composition is formulated to deliver said testosterone through a mucosal surface of the mammal, and to provide a blood serum concentration ratio of testosterone to 5 α -dihydrotestosterone (DHT) of about 10 to 1 or greater in the bloodstream of said mammal.

27. The controlled, sustained release progressive hydration composition of claim 26, wherein said composition is formulated to deliver said testosterone via the mammal's buccal cavity.

28. The controlled, sustained release progressive hydration composition of claim 26, wherein said composition is formulated to deliver said testosterone via the mammal's vaginal cavity.

29. The method of claim 7, wherein said mucosal surface is the mammal's vaginal cavity.

30. The method of claim 7, wherein said mucosal surface is the mammal's buccal cavity.